UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte C. ALEXANDER TURNER, JR., GREGORY DONOHO, XIAOMING WANG, ERIN HILBUN, BRIAN ZAMBROWICZ, and ARTHUR T. SANDS

Appeal No. 2005-2379
Application No. 09/689,911

ON BRIEF

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-8, all of the claims remaining. Claim 3 is representative and reads as follows:

1. An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO:2.

The examiner relies on the following references:

Bork et al., "Go hunting in sequence databases but watch out for the traps," TIG, Vol. 12. No. 10, pp. 425-427 (1996)

Smith et al., "The challenges of sequence annotation or 'The devil is in the details'," Nature Biotechnology, Vol. 15, pp. 1222-1223 (1997)

Doerks et al., "Protein annotation: detective work for function prediction," TIG, Vol. 14, No. 6, pp. 248-250 (1998)

Brenner, "Errors in genome annotation," TIG, Vol. 15, No. 4, pp. 132-133 (1999)

Florén et al., "Galanin receptor subtypes and ligand binding," Neuropeptides, Vol. 34, No. 6, pp. 331-337 (2000)

Bork, "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," Geonome Research, Vol. 10, pp. 398-400 (2000)

Skolnick et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era," Trends in Biotech, Vol. 18, No. 1, pp. 34-39 (2000)

Claims 1-8 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as lacking patentable utility. We affirm.

Background

The specification discloses polynucleotides encoding human peptides (referred to generically as a "novel human proteins" or NHPs) that "share sequence similarity with mammalian galanins." Page 1. One of the disclosed polynucleotides encodes a polypeptide of 141 amino acids (with the amino acid sequence shown in SEQ ID NO:2). Page 2, lines 14-16.

The specification states that

> [g]alanins are biologically active peptides that are present in the central and peripheral nervous system and are upregulated after spinal injury and in response to estrogen. Galanins also include neuropeptides that control a broad variety of biological activities. . . . The first 14 residues of mature galanin proteins are highly conserved.

> [G]alanins have been associated with, inter alia, regulating body weight, modulating behavior, treating pain, inflammation, neuronal repair, Alzheimer's dementia, inflammatory bowel disorders, and infectious disease.
>
> . . . Unlike other known galanins, the presently described sequences differ at amino acid 14 of the consensus sequence shared by other galanins (replacing an H in the consensus with a V. . .).

Pages 1-2.

The specification does not disclose what role the protein of SEQ ID NO:7 plays in any biological process, but contemplates "processes for identifying compounds that modulate, i.e., act as agonists or antagonists, of NHP expression and/or NHP activity . . . . Such compounds can be used as therapeutic agents for the treatment of a wide variety of symptoms associated with biological disorders or imbalances." Page 2.

The specification states that "[t]he invention also encompasses . . . transgenic animals that express a NHP transgene, or 'knock-outs' (which can be conditional) that do not express a functional NHP." Page 2. The specification does not provide any working examples in which transgenic animals or "knock-outs" were actually made.

The NHP protein is disclosed to be useful "in assays for screening for compounds that can be used as pharmaceutical reagents useful in the therapeutic treatment of mental, biological, or medical disorders and disease." Pages 12-13.

Discussion

The examiner rejected all of the claims as lacking a disclosed utility sufficient to satisfy 35 U.S.C. § 101.[1] The examiner bears the initial burden of showing that a

[1] The examiner also rejected all of the claims under 35 U.S.C. § 112, first paragraph, for lack of enablement, but that rejection is merely as a corollary of the finding of lack of utility. See the Examiner's Answer, page 8. Therefore, our conclusion with respect to the § 101 issue also applies to the § 112 issue.

claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed

ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, the examiner found the specification's disclosure to be inadequate because, among other things, "neither the specification nor the prior art provides for the physiological significance of the disclosed NHP polypeptide." Examiner's Answer, page 6. See also pages 7-8:

> The instant claims are drawn to a nucleic acid encoding a polypeptide which has an as yet undetermined function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification as NHP, the instant invention is incomplete. In the absence of knowledge of the natural substrate or biological significance of this protein, there is no immediately obvious patentable use for it.

Appellants argue that "the presently claimed sequence shares 100% identity at the amino acid level with the first 98 amino acids of a sequence that is described in a journal article by Ohtaki et al. (J. Biol. Chem. 274:37401-37405, 1999) . . . as 'Human Galanin- like Peptide (GALP)." Appeal Brief, pages 4-5.

Appellants' reliance on the Ohtaki reference is misplaced, because the reference was published after the effective filing date of the instant application. This application "claims the benefit of U.S. Provisional Application Number 60/158,848 which was filed on October 12, 1999." Specification, page 1. Ohtaki was published December 24, 1999. Appellants have presented no evidence to show that Ohtaki represents the state of the art as of this application's effective filing date.

Post-filing date evidence can be relied on to support utility only where it shows the state of the art as of the application's effective filing date. See In re Hogan, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977) ("[U]se of later publications as evidence of the state of art existing on the filing date of an application" is acceptable.). See also In re Glass, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974): "[A]pplication sufficiency under § 112, first paragraph, must be judged as of its filing date. It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file." Although both Hogan and Glass concerned enablement, the same standard applies to utility under § 101. See In re Brana, 51 F.3d 1560, 1567 n.19, 34 USPQ2d 1436, 1441 n.19 (Fed. Cir. 1995) ("Enablement, or utility, is determined as of the application filing date.").

The post-filing reference cited by Appellants does not appear to reflect the state of the art as of October 12, 1999, the effective filing date of the instant application. Therefore, the evidence in that reference – evidence that became known to those

skilled in the art after the instant application was filed – cannot be relied on to support the patentable utility of the instant claims.

Appellants also argue that

> the specification as originally filed indicates that the presently claimed galanin family sequences are involved in a number of functions, including a role in 'inflammation' (specification at page 1, line 34). Appellants also pointed out that this phenotype was confirmed in genetically engineered mice that lack the murine homolog of the presently claimed sequence. . . . Appellants stated that the homozygous knockout animals showed an increase in total white blood cells compared to a wild-type control, consistent with, as set forth in the instant application, the stated role of this protein in inflammation.

Appeal Brief, pages 5-6. Appellants conclude that "as the physiological role of the presently claimed sequence in inflammation, as set forth in the specification as originally filed, has been confirmed by Appellants in knockout animals that lack the orthologous sequence corresponding to the claimed sequence . . . the present claims clearly meet the requirements of 35 U.S.C. § 101." Id., page 7.

Appellants, however, have pointed to no evidence in the record that shows the data on which their argument is based. It is the applicant's burden to identify the evidence he relies on and explain how that evidence supports his position. See, e.g., In re Borkowski, 505 F.2d 713, 718, 184 USPQ 29, 33 (CCPA 1974); In re Langer, 503 F.2d 1380, 1395, 183 USPQ 288, 299 (CCPA 1974) ("Despite the fact that appellant had the burden of rebutting the prima facie case, appellant submitted no evidence to support the foregoing argument, and counsel's argument cannot take the place of evidence.").

Here, Appellants have pointed to no evidence in the record that supports their argument that the disclosed galanin-related polypeptide is involved in inflammation. We

have reviewed the record and have found no description of the knock-out mice referred to in Appellants' argument. Since Appellants' argument has no apparent evidentiary basis, we find the argument unpersuasive.

We do not mean to suggest that Appellants are asserting as fact the results of experiments they have not done: presenting prophetic examples as if they were actual results can be inequitable conduct. See Novo Nordisk Pharms., Inc. v. Bio-Technology General Corp., 424 F.3d 1347, 1359 (Fed. Cir. 2005) ("The district court based its finding of inequitable conduct with respect to prosecution of the '856 application on Novo's failure to disclose to the PTO that Example 1 . . . had never actually been performed.") and id. at 1362 ("We therefore affirm the district court's ruling that the '352 patent is unenforceable due to inequitable conduct.").

We are not accusing Appellants of breaching their "duty of candor and good faith," 37 CFR § 1.56(a), but we must base our decision on evidence, not assertions, and the evidence must be in the record for us to evaluate. Since Appellants have pointed to no evidence of record that supports their argument, we have nothing to evaluate and no choice but to find Appellants' argument unpersuasive.

Appellants also argue that the claimed polynucleotides are useful for "tracking the expression of the genes encoding the described proteins" (Appeal Brief, page 8); that they are useful in mapping human chromosomes (id., page 12); and that they are useful for defining exon splice-junctions (id.).

We find that none of these uses meet the requirements of § 101. In this case, as in Fisher, the generic uses asserted by Appellants – assessing gene expression, mapping human chromosomes, and defining exon splice-junctions – are neither

substantial nor specific. Like in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher, 421 F.3d at 137376 USPQ2d at 1231 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at 1374, 76 USPQ2d at 1232.

Summary

The specification does not disclose a specific and substantial utility for the claimed nucleic acids, as required by 35 U.S.C. § 101. We therefore affirm the examiner's rejection of claims 1-8.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

EG/jlb

Lexicon Genetics Incorporated
8800 Technology Forest Place
The Woodlands, TX 77381-1160